
APPLICATION
FOR UNITED STATES PATENT

TISSUE SEALING ELECTROSURGERY DEVICE
AND METHODS OF SEALING TISSUE

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1 SPECIFICATION

2 BACKGROUND OF THE INVENTION

3 This invention relates to medical instruments, and more particularly to
4 electrosurgical devices, and methods of manipulating tissue as, for example, by cutting
5 the tissue.

6 Description of the Related Art

7 High-frequency alternating current was used to cut and coagulate human
8 tissue as early as 1911. Current generators and electrode tipped instruments then
9 progressed such that electrosurgical instruments and current generators are available
10 in a multitude of configurations for both open procedures and endoscopic procedures,
11 with microprocessor-controlled currents typically on the order of 500KHz.
12 Radiofrequency (RF) catheter ablation of brain lesions began in the 1960s, and RF
13 ablation of heart tissue to control supraventricular tachyarrhythmias began in the
14 1980s. Thus, electrical energy, including but not limited to RF energy, is a known tool
15 for a variety of effects on human tissue, including cutting, coagulating, and ablative
16 necrosis, with and as a part of electrically conductive forceps. Bipolar and monopolar
17 currents are both used with electrosurgical forceps. With monopolar current, a
18 grounding pad is placed under the patient. A recent example of an electrically

1 energized electrosurgical device is disclosed in U.S. Patent No. 5,403,312 issued on
2 April 4, 1995 to Yates et al., and the disclosure is incorporated by reference.

3 SUMMARY OF THE INVENTION

4 An object of the present invention is to provide an electrosurgery tissue
5 sealing medical device which may and also may not be a forceps.

6 Another object of the present invention is to provide an electrosurgery tissue
7 sealing device such as a forceps that seals tissue by a unique flow of an electrolytic
8 fluid or solution to the manipulating portions of the device in combination with
9 energization of the solution with electrical energy. The effect of the solution and
10 energy may be enhanced with pressure. The solution is brought into contact with and
11 infuses the tissue. The solution may include saline as well as other non-toxic and toxic
12 electrolytic solutions, and may be energized with RF electrical energy. The body of
13 the device itself may or not be energized.

14 The solution provides at least in part the beneficial functions and effects of the
15 instrument. As preferred, pressure on the tissue is applied, and most preferably the
16 effect of pressure is optimized, as by applying pressure across the tissue to be effected
17 that is substantially uniform.

18 Another object of the invention is to provide an electrosurgery medical device

1 as described, and methods of sealing tissue, in which tissues are sealed against flow
2 of fluids including air. With the invention, for example, lung tissue is aerostatically and
3 hemostatically sealed, with the tissue adjacent the sealed tissue retaining blood and air.

4 Another object of the invention is to provide an electrosurgery medical device
5 that may take the form of open surgery forceps of a variety of specific forms, or
6 endoscopic forceps, also of a variety of forms.

7 A further object of the invention is to provide an electrosurgery medical device
8 as described, in which the electrolytic solution by which the instrument functions is
9 infused from the device onto and/or into the tissue along the operative portions of the
10 device. With and without applied pressure, the solution coagulates and additionally
11 seals tissue, as a result of being energized by RF energy, and also envelopes the
12 operative portions of the device in solution all during manipulation of tissue,
13 substantially completely preventing adherence between the instrument and tissue,
14 substantially without flushing action.

15 In a principal aspect, then, the invention takes the form of an enhanced
16 solution-assisted electrosurgery medical device comprising, in combination, co-
17 operating device jaws including jaw portions for manipulating tissue, and a plurality
18 of solution infusion openings defined and spaced along each of the jaw portions, for

1 receiving solution and infusing solution onto and into the tissue along said jaw
2 portions. While the device is contemplated with and without grooves, as preferred,
3 the device further comprises at least one, and most preferably, many, longitudinal
4 grooves along at least one and most preferably, both, of the jaw portions. Also most
5 preferably, the solution infusion openings are located on the inside faces of the jaw
6 portions, adjacent to and most preferably in the groove or grooves. The solution
7 exiting the openings separates substantially all the operative surfaces of the device
8 from tissue, substantially completely preventing adherence between the operative
9 surfaces and tissue. The solution also aids in coagulation.

10 Coagulation aside, the invention causes hemostasis, aerostasis, and more
11 generally, "omnistasis" of substantially any and all liquids and gases found in tissue
12 being treated, such as lymphatic fluids and methane, as well as blood and air. These
13 broader effects are understood to result from such actions as shrinkage of vasculature
14 with and without coagulation, and without desiccation and carbonization.

15 Also as preferred, the operative portions of the device may take the form of
16 a circular, semicircular or other regular and irregular geometric shape, to contain
17 and/or isolate tissue to be affected and perhaps resected. As an example, with an
18 enclosed geometric shape such as a circle, tissue surrounding lesions and/or tumors

1 of the lung may be aerostatically and hemostatically sealed, resulting in an isolation
2 of the lesions and/or tumors for resection. Lung function is retained. For adaption to
3 unique tissue geometries, the operative portions of the device may be malleable, to be
4 manipulated to substantially any needed contour. For procedures including resection,
5 the device may include an advanceable and retractable blade, or additional functional
6 structures and features.

7 These and other objects, advantages and features of the invention will become
8 more apparent upon a reading of the detailed description of preferred embodiments
9 of the invention, which follows, and reference to the drawing which accompanies this
10 description.

BRIEF DESCRIPTION OF THE DRAWING

The accompanying drawing includes a variety of figures. Like numbers refer to like parts throughout the drawing. In the drawing:

Fig. 1 is a schematic diagram of the key elements of an electrical circuit according to the invention;

Fig. 2 is a perspective view of an endoscopic forceps according to the invention;

Fig. 3 is a detail view of a portion of the forceps of Fig. 2; and

Fig. 4 is a perspective view of a modification of the embodiment of Fig. 2;

Fig. 5 is a second modification, of the embodiment of Fig. 4, shown partially broken away;

Fig. 6 is a perspective view of an open surgery forceps according to the invention;

Fig. 7 is a detail view of a portion of the forceps of Fig. 6, partially broken away;

Fig. 8 is a schematic view of preferred saline supply equipment for the invention;

Fig. 9 is a perspective view of a portion of the jaws of an alternative device;

- 1 Fig. 10 is a perspective view similar to Fig. 9 of another alternative device;
2 Fig. 11 is a cross-sectional view along line 11-11 of Fig. 9; and
3 Fig. 12 is a perspective view of yet another alternative device.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

Electrosurgery uses electrical energy to heat tissue and cause a variety of effects such as cutting, coagulation and ablative necrosis. The heat arises as the energy dissipates in the resistance of the tissue. The effect is dependent on both temperature and time. Lower temperatures for longer times often yield the same effect as higher temperatures for shorter times. Normal body temperature is approximately 37°C. No significant long-term effect is caused by temperatures in the range of 37°C to 40°C. In the range of 41°C to 44°C, cell damage is reversible for exposure times less than several hours. In the range of 45°C to 49°C, cell damage becomes irreversible at increasingly short intervals. The following table states expected effects at higher temperatures:

Temperature (°C)	Effect
50-69	Irreversible cell damage - ablation necrosis.
70	Threshold temperature for shrinkage of tissue. (Some collagen hydrogen bonds break at 60-68; those with cross-linkages break at 75-80.)
70-99	Range of coagulation. Hemostasis due to shrinkage of blood vessels.
100	Water boils.

Desiccation as fluid is vaporized.
Dependent on the length of time
during which heat is applied,
carbonization may occur, and at higher
temperatures, occurs quickly.

This table is not intended as a statement of scientifically precise ranges above and below which no similar effects will be found, and instead, is intended as a statement of generally accepted values which provide approximations of the ranges of the stated effects. Limitation of the appended claims in accordance with this and the further details of this description is intended to the extent such details are incorporated in the claims, and not otherwise.

As a consequence of the foregoing effects, preferred "soft" coagulation occurs at temperatures slightly above 70°C. Heat denatures and shrinks tissues and blood vessels, thereby leading, as desired, to control of bleeding. Cells are generally not ruptured. "Soft" coagulation is generally assured with voltages below 200 peak Volts. Sparks are avoided. "Forced" coagulation can be accomplished with bursts of electrical energy. Electric arcs are generated. Deeper coagulation is achieved, at the cost of some carbonization and an occasional cutting effect. Spray coagulation is also possible. Tissue cutting occurs by desiccation, when the concentration of electrical energy, also referred to here as energy density, is acute, and the temperature of tissue

1 is raised above 100°C.

2 For both coagulation and cutting by electrical energy, a sine wave waveform
3 is employed, with a frequency of about 500 kHz. For cutting, increasing voltage to
4 as much as 600 peak Volts leads to higher spark intensity which results in deeper cuts.
5 Frequencies above 300,000 Hz avoid stimulating nerve and muscle cells, and generally
6 assure that the effect on tissue is substantially purely thermal.

7 In contrast with the RF energy tissue-cutting electrosurgery tools of the past,
8 significant purposes of the present invention are to provide a mechanism of avoiding
9 desiccation of tissue at the electrode/tissue interface and to achieve sealing of tissues.
10 By "sealing," the effects of hemostasis, or arresting of bleeding; "aerostasis," or
11 arresting of the passage of air, and closure of tissues such as blood vessels against
12 larger-scale passage of blood, among other effects, are intended. More specifically,
13 the effect of sealing at the cellular level is a primary focus, as is sealing at the vascular
14 level.

15 Referring to Figure 1, key elements of a preferred electrical circuit according
16 to the invention include an electrosurgical unit 10, a switch 12, and electrodes 14, 16.
17 An effect is created on tissue 18 of a body 20. One electrode such as electrode 14 acts
18 as a positive or active electrode, while the other such as electrode 16 acts as a

1 negative or return electrode. Current flows directly from one electrode to the other
2 primarily through only the tissue, as shown by arrows 22, 24, 26, 28, 29. No pad is
3 needed under the patient. This is a bipolar configuration.

4 Referring to Fig. 2, a forceps 30 according to the invention is an endoscopic
5 forceps, and includes manual handles 32, 34, an elongated shaft 36, and jaws 38, 40.
6 The handles 32, 34 pivot together and apart and through a suitable mechanism (not
7 shown; present in the incorporated prior art) control the jaws 38, 40 to also pivot
8 together and apart about a pivot connection 42. Referring to Fig. 3, each jaw 38, 40
9 is formed in two parts, hinged together. The jaw 38 includes a link portion 44
10 connected directly to the forceps shaft 36, and the jaw 40 includes a link portion 46
11 also connected directly to the forceps shaft 36. A jaw portion 48 hingedly fastened to
12 the jaw link portion 44 completes the jaw 38; a jaw portion 50 hingedly fastened to
13 the jaw link portion 46 completes the jaw 40.

14 As stated in the background of the invention, a wide variety of alternatives to
15 the structure described and shown in Fig. 2 are possible. Prominent examples from
16 those incorporated include the structures of U.S. Patent No. 5,403,312 (Yates et al.)
17 issued April 4, 1995; U.S. Patent No. 5,395,312 (Desai) issued March 7, 1995; and
18 U.S. Patent No. 5,318,589 (Lichtman et al.) issued June 7, 1994

1 Still referring to Fig. 3, a solution supply tube 52 supplies electrolytic solution
2 to an electrode strip 47 along the jaw portion 48, as will be described. A solution
3 supply tube 54 supplies electrolytic solution to a similar strip 49 along the jaw portion
4 50. A wire 56 electrically connects to the solution supply tube 52; a wire 58
5 electrically connects to the solution supply tube 54. All the supplies 52, 54, 56, 58,
6 both solution and electrical, extend from the proximal or manual handle end of the
7 shaft 36, and connect to solution and electrical sources.

8 Referring to Fig. 4, and in a second form of a jaw, designated 140, a jaw
9 portion 150 similar to jaw portion 50 in Fig. 3, includes a longitudinal dimension in
10 the direction of arrow 160. A plurality of longitudinal grooves 162 are spaced side-by-
11 side across the inner face 164 of the jaw portion 150. The grooves 162 extend the full
12 longitudinal length of the jaw portion 150. The same is true of a mirror image jaw
13 portion, not shown. Both jaw portions are incorporated in a structure as in Fig. 3, and
14 could be placed in substitution for jaw portions 48, 50 in Fig. 3. Grooves, not shown,
15 also preferably extend along the corresponding jaw portions 48, 50 of Figs. 2-3.
16 Orientations of the grooves other than longitudinal are considered possible, within the
17 limit of construction and arrangement to substantially retain solution along the
18 operative jaw portions.

1 Bodily tissues to be manipulated have a natural surface roughness. This
2 roughness significantly reduces the area of contact between the forceps jaws and
3 manipulated tissues. Air gaps are created between conventional smooth-surfaced jaws
4 and tissues. If the jaws were energized when dry, electrical resistance in the tissues
5 would be increased, and the current density and tissue temperature would be
6 extremely high. In practice, tissue surfaces are sometimes wet in spots, and yet tissue
7 wetness is not controlled, such that electrical power is to be set on the assumption the
8 inner jaw surfaces are dry. This assumption is necessary to minimize unwanted arcing,
9 charring and smoke.

10 In contrast, in a forceps according to the invention, whether the jaw portions
11 are grooved or smooth, whether the grooves are longitudinal or otherwise oriented,
12 the jaw portions are uniquely formed of a material such as hollow stainless steel
13 needle tubing such that solution infusion openings 166 may be and are formed in the
14 jaw inner faces such as the inner face 164, as in Fig. 4. Further, the solution supplies
15 52, 54 shown by example in Fig. 3 may and do open into the openings 166, to supply
16 solution to the openings 166. As most preferred, the openings 166 are laser drilled,
17 and have a diameter in a range centered around four thousandths (0.004) of an inch,
18 and most preferably in a range from two to six thousandths (0.002-0.006) inches.

1 The purpose of the openings 166 is to infuse solution onto and/or into the
2 tissue adjacent to and otherwise in contact with the forceps jaw portions inner
3 surfaces. It is understood the openings are appropriately as small in diameter as
4 described above to assure more even flow among the openings than would otherwise
5 occur. Further, the openings need not be so closely spaced as to mimic the surface
6 roughness as tissues. Microporous surfaces are possibly acceptable, while they are
7 also not necessary. Infusion of fluid through the jaws is to be maintained in a
8 continuous flow during and throughout the application of RF energy in order for the
9 desired tissue effect to be achieved.

10 With the described structure and similar structures and methods within the
11 scope of the invention, numerous advantages are obtained. Deeper and quicker
12 coagulation is possible. The conductive solution infused onto and into the tissues
13 maintains relatively consistent maximal electrical contact areas, substantially
14 preventing hot spots and allowing higher power than soft coagulation. Little to no
15 arcing, cutting smoke or char is formed. Jaw and tissue surface temperatures are
16 lower than otherwise, resulting in significantly less adhesion of tissue to jaw surfaces,
17 and substantially no desiccation. One mode of coagulation may be used in the place
18 of the three modes soft, forced, and spray. Coagulation is possible of even the most

1 challenging oozing tissues such as lung, liver and spleen tissues. Coagulation is more
2 precise, where other coagulation modes sometimes spark to the sides and produce
3 coagulation where not desired.

4 Also, and importantly, electrosurgical cutting by desiccation may be avoided,
5 and tissue sealing achieved. As desired, tissue sealing may occur alone, or be
6 accompanied with mechanical cutting, as by a retractable and advancable blade as in
7 U.S. Patent No. 5,458,598, and as with blade 1210 in Fig. 12, or otherwise. The
8 tissue sealing itself is understood to occur by flow of electrolytic solution to the
9 manipulating portions of the forceps in combination with energization of the solution
10 with electrical energy, and when included, in combination with pressure on, or
11 compression of, the tissue. Compression of tissue is understood to deform tissues into
12 conditions of sealing of tissues and especially vasculature. Compression of tissue
13 followed by application of solution and energy is understood to permanently maintain
14 compressed deformation of tissue, when present, and to shrink tissue and cause
15 proteins to fix in place. Additional understanding of others is provided in the Yates
16 et al. patent referenced above.

17 The body of the forceps itself may or not be energized. As most preferred, the
18 solution primarily provides the beneficial functions and effects of the instrument. The

effectiveness and extent of the tissue sealing is a function primarily of the type of tissue being manipulated, the quantity of electrolytic solution supplied to the tissue, and the power of the electrical energy supplied to the solution. Tissues not previously considered to be suitable for manipulation, as by cutting, are rendered suitable for manipulation by being sealed against flow of fluids, including bodily fluids and air. With the invention, for example, lung tissue may be cut after sealing, with the tissue adjacent the sealed tissue retaining blood and air. Examples of the principal parameters of specific uses of the invention are provided in the following table. It is understood that the combined consequences of the parameters are that energy density in the tissue to be treated is in a range to effect sealing of the tissue. However, in general, a power output of 7 to 150 watts is preferred.

Fluid Quantity	Power	Tissue	Effect
2 cc's per minute per electrode	20 watts for 30 seconds	1 cm diameter vessel	hemostasis through the vessel
2 cc's per minute per electrode	30 watts for 45 seconds	lung tissue	hemostasis and aerostasis
4 cc's per minute per electrode	40 watts for 90 seconds	2 cm thickness liver tissue	hemostasis

In the examples for which the table is provided, the electrolytic solution is saline. In the first example, the device in use was a device as in Fig. 2, with electrodes

of 16 gauge tubing, 1 cm long. The tool in use in the second and third examples was a forceps as in Fig. 6, with jaw portions 348, 350, to be described, 4 mm wide and 2.8 cm long. No desiccation was observed at the tissue/electrode interface. The device of Fig. 2 is preferred for vessel closure.

A wide variety of the currently installed electrosurgical generators could and will provide proper waveforms and power levels for driving the described forceps. The waveforms need only be sine waves at about 500 kHz, and the power need only be about 30 or more watts. As example of available generators, Valleylab generators are acceptable and widely available.

The electrolytic solution supplied to the forceps need only be saline, although a variety of non-toxic and toxic electrolytic solutions are possible. Toxic fluids may be desirable when excising undesired tissues, to prevent seeding during excision. Use of a pressure bulb is possible, as shown in Fig. 8. A flexible reservoir such as an intravenous (IV) bag 410 is surrounded with a more rigid rubber bulb 412 that is pressurized with air through an attached squeeze bulb 414. The reservoir is filled with solution through an injection port 416. An outflow line 418 has a filter 420 and a capillary tube flow restrictor 422 to meter flow. A clamp or valve 424 and connector 426 are also provided. A typical flow rate is one to two (1-2) cc/min at a maximum

1 pressure of approximately sixteen pounds per square inch (16 psi)(52 mmHg). An
2 example of opening diameters, numbers, and flow rate is as follows: opening
3 diameter, 0.16 mm; number of openings, 13 per cm; and flow rate, 2 cc's per minute.
4 A long slit has also been used and found acceptable. In this embodiment, flow rates
5 of 0.01 to 50 cc/min are preferred.

6 It is understood that highly significant to the invention is the spacing of a
7 plurality of solution openings along the jaw inner surfaces. Single openings as in Ohta
8 et al., that effectively pour fluid adjacent one portion of forceps, are generally not
9 considered suitable or effective. Openings along outer surfaces of the jaws, opposite
10 inner surfaces, are also generally not considered suitable or effective.

11 Referring to Figs. 4 and 5, the configurations of the most preferred solution
12 openings are disclosed. Referring to Fig. 5, in a jaw 240, longitudinally spaced
13 openings 166 are rotated from those shown in Fig. 4, in a jaw portion 250, to turn the
14 openings away from most direct contact with tissues, and more carefully eliminate any
15 unintended plugging of the openings. Electrical insulators 268 in the form of
16 elongated strips extend alongside the tubes which include the openings 166.

17 Referring to Fig. 6, open surgical forceps 330 include jaws 338, 340 with jaw
18 portions 348, 350. As with jaw portion 350 in Fig. 7, the jaw portions 348, 350

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include spaced solution infusion openings 166 in the central longitudinal groove of a plurality of grooves 162. A central channel 370 of both jaw portions 348, 350, as shown relative to jaw portion 350 in Fig. 7, supplies solution to the openings 166 from solution supplies 52, 54. As with the endoscopic forceps of Figs. 2-5, the open surgical forceps 330 benefits from the unique enhancement of electrosurgical functions through the infusion of electrolytic solutions onto and into tissues through the spaced, laser drilled, solution infusion openings in the grooves 162.

Referring to Figs. 9 and 10, open surgical devices 430 and 530 also include jaws 438, 440 and 538, 540, respectively. The jaw portions of these devices are curved, and in the case of device 430, circular, to adapt the invention to specialized surgical situations of tissue manipulation, such as those in which fluid flow is to be terminated all around a tissue to be isolated and resected or excised. An example of such a tissue is a lesion or tumor of lung tissue. In endoscopic or open surgery, such lesions or tumors may be encircled and/or isolated, surrounding tissue sealed, and the lesions or tumors thereafter resected. Preferably, a one centimeter margin is resected about any lesion or tumor, with the lesion or tumor. As shown, the devices 430, 530 are formed of substantially square cross-section tubing, best shown in the cross-sectional drawing of Fig. 11. As most preferred, the tubing incorporates a central,

1 depressed, cross-sectionally rectangular, and elongated groove 462 and equilaterally
2 spaced, cross-sectionally triangular, parallel, and elongated outer grooves 464, 465.
3 Laser drilled openings 466, similar to openings 166 described above, are located in
4 and spaced along the central groove 462.

5 Alternate cross-sectional shapes of tubing may be employed, as exemplified
6 in Fig. 12. Flatter operative, e.g., inner faces of tubing are preferred within limits of
7 constructing and arranging the operative faces to facilitate firm grasping and holding
8 of tissue. Non-operative surfaces, being less of concern, may adapt to a variety of
9 contours for a variety of alternate reasons. Further, malleable tubing may be
10 employed, to permit the surgeon to shape the operative portions of the invented
11 devices to specific physiological situations.

12 The infusion of conductive solutions, referred to here also as electrolytic
13 solutions, simultaneously with the application of RF energy to tissues is discussed in
14 further detail in U.S. Patent No. 5,431,649 entitled "Method and Apparatus for R-F
15 Ablation," in the name of Peter M.J. Mulier and Michael F. Hoey; in U.S. Patent No.
16 5,609,151, entitled "Method and Apparatus for R-F Ablation," in the name of Peter
17 M.J. Mulier. The foregoing patents are commonly assigned to the assignee of the
18 present invention, and are incorporated by reference here.

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1 The preferred embodiments, and the processes of making and using them, are
2 now considered to be described in such full, clear, concise and exact terms as to
3 enable a person of skill in the art to make and use the same. Those skilled in the art
4 will recognize that the preferred embodiments may be altered and modified without
5 departing from the true spirit and scope of the invention as defined in the appended
6 claims. For example, if the invented device is incorporated in forceps, the forceps
7 may be varied in a range from excision and cutting biopsy forceps, to endoscopic
8 forceps, dissecting forceps, and traumatic, atraumatic and flexible endoscopic
9 grasping forceps. The jaws may close into full and tight contact with each other, or
10 close into spaced relationship to each other, to accommodate tissue for purposes
11 other than cutting. As expressed above, parallel spaced relationship is considered most
12 preferably for uniformity of application of pressure across tissue to be affected.

13 A variety of features such as jaw serrations, single acting and double acting
14 jaws, closing springs, ratchet locks, fingertip rotation rings, color coding and smoke
15 aspiration may or may not be included with the features described in detail. Devices
16 according to the invention may be constructed and arranged to grasp, hold, fix, cut,
17 dissect, expose, remove, extract, retrieve, and otherwise manipulate and treat organs,
18 tissues, tissue masses, and objects. Endoscopic forceps according to the invention may

1 be designed to be used through a trocar. Bipolar and monopolar currents may both
2 be used. With monopolar current, grounding pads may be placed under patients. The
3 described grooves may be eliminated in favor of alternative grooves.

4 For purposes of the appended claims, the term "manipulate" includes the
5 described functions of grasping, holding, fixing, cutting, dissecting, exposing,
6 removing, extracting, retrieving, coagulating, ablating and otherwise manipulating or
7 similarly treating organs, tissues, tissue masses, and objects. Also for purposes of the
8 appended claims, the term "tissue" includes organs, tissues, tissue masses, and
9 objects. Further for purposes of the appended claims, the term "electrical energy
10 sufficient to affect tissue" includes electrical energy sufficient to raise tissue
11 temperature to cause non-reversible effect on tissue as described above.

12 To particularly point out and distinctly claim the subject matter regarded as
13 invention, the following claims conclude this specification.